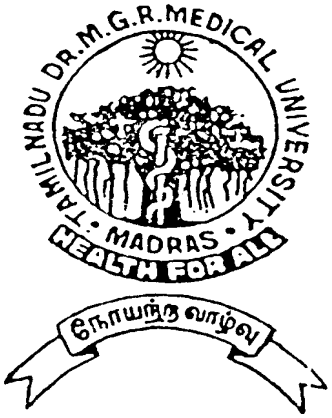
EFFECTIVENESS, TOLERABILITY AND SAFETY OF INTRAVENOUS IRON SUCROSE VERSUS INTRAMUSCULAR IRON DEXTRAN IN PREGNANCY AND POSTPARTUM

DISSERTATION SUBMITTED FOR

M.D DEGREE (OBSTETRICS AND GYNAECOLOGY) BRANCH III

MARCH 2009



THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

CHENNAI

CERTIFICATE

This is to certify that the dissertation titled "Effectiveness, tolerability and safety of intravenous iron sucrose versus intramuscular iron dextran in pregnancy and postpartum" submitted by Dr. P.Selvi to the Faculty of Obstetrics and Gynaecology, The Tamilnadu Dr. M.G.R. Medical university, Chennai in partial fulfillment of the requirement for the award of M.D. Degree (Obstetrics and Gynaecology) is a bonafide research work carried out by her under our direct supervision and guidance.

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D E C L A R A T I O N

I. ***Dr. P. Selvi,*** *solemnly declare that the dissertation titled* ***"Effectiveness, tolerability and safety of intravenous iron sucrose versus intramuscular iron dextran in pregnancy and postpartum"*** *has been prepared by me.*

This is submitted to the ***Tamilnadu Dr. M.G.R. Medical University****, Chennai in partial fulfillment of the rules and regulations for the M.D. Degree Examination in Obstetrics and Gynaecology.*

Place : Madurai

Date : ***Dr. P. Selvi***

A C K N O W L E D G E M E N T

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INTRODUCTION

INTRODUCTION

Anemia is defined by world health organisation as hemoglobin levels <11gm/dl. It is one of the most serious global public health problem affects 52% of pregnant women in developing and 23% in developed countries (Cochrane data review).

In under developed countries anemia is a major contributory factor to maternal morbidity, mortality and higher perinatal mortality rate.

Anemia in pregnancy is associated with an increased risk of preterm delivery, low-birth weight and maternal mortality (Harvey LJ – Dainty JR, Hollands WJ, et al).

Iron is an essential component of Hb (ie Oxygen carrying pigment in the Blood). The pregnant women needs 1000mg of iron all through pregnancy i-e 3.5 mg / day to maintain iron balance. This demand during later half of pregnancy and for several weeks after delivery increases to about 6.7 mg/day.

Iron is essential to life because of its unique ability to serve as both an electron donor and acceptor.

In order to identify anemia in pregnancy, an accurate method for measuring Hb level is needed, many clinics in developing countries especially those in sub-saharan Africa, rely only

on conjunctival inspections.

WHO colour scale might still be useful especially at primary health care level as a screening tool despite observed limitations in accuracy. The routine measurement of serum ferritin, the best indicator of body iron stores than Hb concentration is unrealistic for most of the low-income groups.
(Who reproductive health library; Geneva ; WHO).

Various forms of Oral, intramuscular and intravenous preparations of iron have been used to correct iron deficiency anemia in pregnancy and puerperium. But they are associated with significant side effects and not possible to achieve target raise in Hb level in limited period.

Although the best method of treating anemia has not been clarified, oral treatment is in theory the most feasible to use. But side effects of oral iron or women's dislike of the tablets owing to smell or taste have been blamed for treatment failure.
(walraven G,and candio F, treatments for iron deficiency anemia in pregnancy)

Mostly anecdotal evidence suggests that I.V and I.M iron administration is associated with allergic reactions. Compared with I.M iron, I.V. iron sucrose significantly increased hematological indices with less side effects.
(Cochrane Database syst Rev, 2006 ; 3; CD004736)

Iron sucrose complex is a newer drug used intravenously for correction of iron deficiency anemia with less side effects and able to raise the Hb to satisfactory level.

This was the study comparing the effectiveness, tolerability and safety of the two drugs intravenous iron sucrose and intramuscular iron dextran in the treatment of iron deficiency anemia in pregnant and postpartum women.

AIM OF THE STUDY

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1. To determine the efficacy, tolerability of intravenous iron sucrose in the treatment of iron deficiency anemia during pregnancy and postpartum compared to intramuscular iron dextran.

2. To determine the safety of intravenous iron sucrose in the treatment of iron deficiency anemia during pregnancy and postpartum compared to intramuscular iron dextran.

REVIEW OF LITERATURE

Al Momen et al conducted a prospective, open-label controlled trial in 111 pregnant women with iron deficiency anemia (Hb : <9gm/dl) and divided into 2 groups. Intravenous group (N. 55) and intramuscular group. Intravenous iron sucrose was administered as an infusion of single 100mg dose in normal saline every 1 to 3 days.

Controls received I.M iron dextran (100mg on alternate days) till the calculated dose was reached. Intravenous iron therapy resulted in higher levels of Hb, with the time to achieve maximum Hb in shorter period compared with controls. No serious adverse effects were noted in iron sucrose group whereas 6% of patients could not tolerate I.M iron dextran, who excluded from the study. 30% of patients in the control group had disturbing G1 symptoms and 32% were non complaint.

Wali A, MushtaqA, Nilofer.

(Journal Pakistan med. Assoc. 2002 sep 52(9) : 392 – 5)

A prospective comparative study, total number of 60 pregnant women with gestational age of 12 – 34 wks with iron deficiency were included, and divided into 2 groups. Group A (N: 30) received intra venous iron sucrose according to recommended dose containing 500mg of iron sucrose for storage, Group B (n=30) received intramuscular iron dextran. Mean Hb in group A was 8.0+/- 1.1gm/dl and in group B was 8.8+/- 0.9gm/dl. In group A and B initial Hb was assesed 3 weeks after therapy which showed an average rise of 2.8gm/dl in group A and

1.4 gm/dl group B. Target Hb level of 11gm/dl was achieved in 80% of group A, 28% of group B patients. In group A one patient had moderate abdominal pain, 2 had weakness and shivering, 3 had phlebitis but none of the patients discontinued the therapy due to adverse effects. In group B majority complained of pain at the injection site, in which 5 patients dropped out from study due to intolerance. They concluded that I.V iron therapy is safe, convenient and more effective than I.M iron therapy, hence I.V iron therapy can replace blood transfusion in antenatal period.

Bhandal .N. Russell. R carried out an prospective randomised trial enrolling 44 women with iron deficiency anemia, defined as Hb < 9gm/dl when measured 24 to 48 hrs after delivery. Group A received (N.22) 200mg I.V on days 2 and 4. Group B (N. 22) received 200mg of oral ferrous sulphate twice a day for 6 wks. Average rise in Hb was 2.5gm/dl on day 5 in I.V group and 0.7gm/dl in oral group. There were no serious adverse effects in I.V group except a few who reported facial flushing and metallic taste during iron infusion. 1/3 of women in oral group had gastrointestinal side effects. They concluded that in women with postpartum iron deficiency anemia intravenous iron sucrose produces higher blood Hb level than oral iron supplementation.

Breyman et al conducted an prospective randomised open study evaluated the efficacy and safety of intravenous iron sucrose with or with out recombinant human erythropoietin in correcting iron deficiency anemia (Hb <10gm/dl) in pregnant women ie. gestational age (> 21 weeks). 20 patients received recombinant human erythropoietin 300 IU/kg and iron sucrose 200mg I.V and 20 patients received I.V iron sucrose 200mg alone twice weekly for 4 weeks till

a target Hb of 11 gm/dl was achieved. There was immediate reticulocyte response and progressive rise in hematocrit in both groups. Higher rise in reticulocyte count and rise in hematocrit was observed in the group that received combination therapy. None required blood transfusion. No serious adverse effects were reported. They concluded that I.V iron sucrose alone should be considered first in resistant iron deficiency anemia during pregnancy. Recombinant human erythropoietin may be considered in severe anemia requiring rapid correction , not responding to I.V iron sucrose.

Lippincott Williams and Wilkins Inc, Pakistan institute of medical science conducted an randomised controlled study in 80 patients with gestational age of 12 – 36 wks from antenatal clinic and 20 patients after postpartum hemorrhage with anemia. Group A received I.V. iron sucrose, group B received I.M iron sorbitol. Group A had mean Hb content of 1.3 + 1.1 gm/dl and group B had 7.9 + 0.9 gm/dl .3 weeks post therapy assesment of Hb showed a total rise of 2.6 gm/dl (Group A) and 1.2 gm/dl (Group B). Target Hb i.e 11gm/dl was achieved in 80% of group A and 20% of group B Patients. Blood transfusion was not required in any group. They concluded that I.V Iron sucrose is safe, convenient and more effective than I.M iron therapy in treatment of Iron deficiency anemia during pregnancy. It can minimise blood transfusion in postnatal women.

Scoff B. Silverstein and George Rodgers

The increased availability of parentral iron preparation should decrease the need to use red cell transfusion in patients with iron deficiency anemia.

Sal-Momen Ak, al-Mechari A; al-Nuaime L et al in 1996 conducted an study comparing I.V iron sucrose and oral ferrous sulphate, they observed that iron sucrose complex group achieved significantly higher Hb level (128.5+/- 6.6gm/dl Vs 111.4 +/- 12.4g/l) in control group. P < or = 0.001. Iron sucrose complex showed no major side effects, but 6% of control group could not tolerate ferrous sulphate. 30% had poor complaince in the control group. They concluded that iron sucrose complex is safe and effective in the treatment of iron deficiency anemia during pregnancy.

Catherine Gay (2005) concluded that although oral iron is the standard treatment for iron deficiency anemia, it is poorly tolerated and has low efficacy in rapid correction of anemia, But I.V iron sucrose is both quick and effective in treating anemia. The average mean rise of Hb was 0.8 gm/dl for oral iron, 3.5 gm/dl for blood transfusion and 3.1gm/dl for I.V iron after 14 days. No serious adverse effects were noted for I.V iron sucrose.

Bayoumeu F, Subiran – Buisset E, Baka NE et al (2002) American Journal of obst. and Gynaecology also observed the effectiveness, safety and tolerability of I.V iron sucrose compared to oral iron for treatment of iron deficiency anemia in pregnant women.

Chamate E. conducted a study on treatment of iron deficiency anemia in pregnancy and immediate puerperium comparing I.V iron sucrose and oral ferrors sulphate and concluded that I.V iron sucrose is safe, convenient and more effective with less adverse effects and it can replace blood transfusion in antenatal period.

Al-Wakeel Js, Malik GH, Atmohaya S, et al 1997, also confirmed the effectiveness of

intravenous iron sucrose in patients with iron deficiency anemia.

Baskin E, Besbas S, Bakkaloglu et al (1999) studied the effect of I.V iron sucrose in hemodialysed children.

Silverberg Ds, Lania A, Peeg G et al (1996), studied the effectiveness, tolerability and safety of I.V iron sucrose for the treatment of anemia of moderate to severe chronic renal failure patients not receiving dialysis.

Gravier A, Descargues G, Marpeace L et al (1999) conducted a study on how to avoid postpartum blood transfusions in Iron deficiency anemia patients, by treating with I.V.Iron sucrose. They concluded that I.V.Iron sucrose is effective in preventing unnecessary blood transfusions in postpartum patients.

Scott B, Silverstein and George M et al (2004) they have observed that increase in Hb first noted after 1 week of iron sucrose administration and serious anaphylactic hypersensitivity 0.002% in I.V iron sucrose group compared to 0.6 – 0.7% in I.M iron dextran group.

Westad S, Backe B, Smedvig E et al studied the effect of intravenous iron sucrose compared with oral ferrous sulphate, they concluded that women who received I.V iron sucrose replenished their iron stores more rapidly and had more symptomatic relief compared to oral iron.

IRON METABOLISM

IRON METABOLISM

Iron

Most of the iron in the diet is in the ferric (fe^{3+}) form, where as it is the ferrous (Fe^{2+}) form that is absorbed. Fe^{3+} will be converted into Fe^{2+} by Fe^{3+} reductase in the brush border of enterocytes (William F. Ganong 21st Edition).

Sources and Contents of Iron

Milk : Human Milk 0.5 mg

(litre) Cow's milk 0.02 – 0.3 mg

Foods : a) Pulses (9 – 11mg)

(80 – 100gms) Cereals (4 – 11mg)

b) Meat, Fish (10 - 25mg)

c) Ripe Banana (0.9mg)

Mango (1.3 mg)

Melon (7.5 mg)

Iron is important is human body because of its occurance in many hematopoietins such as hemoglobin, myoglobin & cytochromes. Digested in diet as heme or non heme iron. (Harper's illustrated Biochemistry – 26th Edition).

Iron Absorption

Normally greater proportion of Dietary heme iron than non-heme iron is absorbed reflecting the Greater importance of heme as source of iron.
(B Jorn Ramussen et al 1974).

Almost all iron absorption occurs in the duodenum. Iron absorption is facilitated by reducing substances like ascorbic acid, Amino acids.

Sugars especially fructose increases the absorption and may contribute to dietary hemosiderin of bantus, who consume a diet high in sugar. (Forth and Rummel 1973)

Iron absorption is inhibited by alkalies, phosphates, phytates (maize, wheat), also by mucosal block i.e., gut has a mechanism to prevent entry of excess iron in the body.

Daily iron requirement for menstruating adult female and pregnancy (last 2 trimesters) is 1-2mg and 3-5mg respectively.

Good mixed diet provides 10 to 15 mg of iron/day. Normal absorption of 10% or so is enough to replace the loss but not able to replace the extra demands of body growth. (Harper's illustrated Biochemistry – 26th Edi).

IRON TRANSPORT

Ferrous iron is transported into enterocyte by the apical membrane iron transporter DMT_1. Some form of ferrous iron is stored as ferritin and the remainder is transported out of the enterocytes by basolateral transporter ferroportin I. In the plasma ferrous iron is converted

to ferric form and bound to transferrin. Normally transferrin is about 35% saturated with iron.

Heme is transported into the enterocyte by separate heme transporter (HT), and heme oxidase releases Fe^{2+} from the heme. Some of the Fe^{2+} is converted to Fe^{3+} and bound to ferritin. The rest binds to Basolateral Fe^{2+} transporter ferroportin (FP), and bound to transferrin and stored in the body as ferritin and hemosiderin.

Ferritin containing cells are exfoliated from the mucosal surface at the end of 2-3days life span. (Conrad and Barton 1981)

Transferrin does not cross the placenta but gives up its iron in chorionic villus, Iron is transferred across the placenta against steep concentration Gradient, so it is Enzyme dependent. (Waller Stein 1973)

The plasma transferrin is less than that expected from TIBC. (Vander Heul et al 1972)

In pregnancy this lack of correlation applies even to low transferrin saturation levels. (Charg and Sivasamboo 1973)

STRUCTURE OF HEME :

Heme group consists of Protoporphyrin IX linked to an atom of further coordinate valence bonds, one attached to polypeptide chain and the other for oxygen transport.

First step is condensation of glycine with succinate, this is iron dependent.

Protoporphyrin IX synthesis is inhibited by iron deficiency. (Ganong 21st Edition)

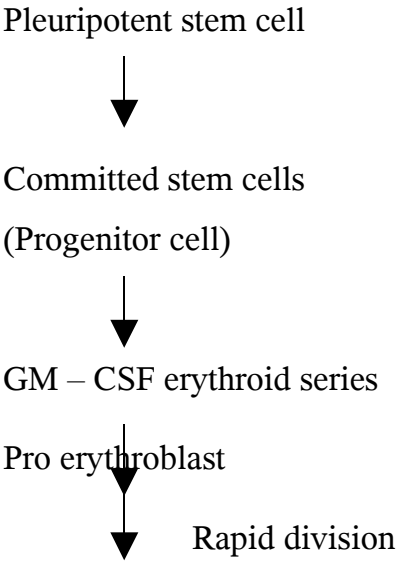
E R Y T H R O P O I E S I S

ERYTHROPOIESIS

Red blood cells production and destruction are balanced to maintain Hb concentration at normal levels. Red blood cell production is a dynamic process and anemia is a disordered dynamic process. (Dr. Ivor Cavill 6th Congress of European Society of Gynaecology 2005)

Decrease in Hb concentration due to various reasons causes decrease in arterial oxygen carrying capacity, which leads to increased Erythropoietin productions in kidney which stimulated Erythropoiesis.

The reliability of invitro bioassay is dependent on compensating for the modifying influences of other human serum components on erythropoietin activity when invitro procedures are employed to measure erythropoietin in serum. (Dekerk et al 1978. Firkin and Russel 1983)



Basophilic normoblast

Polychromatic normoblast

(Proliferation activity ceases after this stage. Begins to produce Hb in the cell. They are called intermediate normoblast).

Orthochromatic normoblast.

(Final stage of maturation of nucleated red blood cells. Active Hb synthesis occurs in cytoplasm.

Active extrusion of nucleus.

Reticulocyte

(Biconcave discoid shaped, greater volume and diameter than mature red blood cells)

Loss their mitochondria and ribosomes over the course of few days, loss the basophilic tint.

Mature erythrocytes.

Transfusion of blood sufficient to raise the hemoglobin concentration above normal or prolonged inhalation of elevated partial pressure of oxygen results in depression of erythropoiesis in keeping with the expected consequences of such feed back system on regulation. (Lawrence et al 1952)

Anemia in hypothyroidism is caused by hemodilution due to expansion of plasma volume, although some decrease does occur in erythropoietic activity.
(FINCH et al 1970).

IRON DEFICIENCY ANEMIA

Iron deficiency anemia of the most common nutritional deficiency in pregnancy followed by folate deficiency anemia. Out of 150 million deliveries occuring annually in the world, approximately 6,00,000 women die from the complications of pregnancy. Anemia is responsible for 40-60% of maternal deaths in non-industrialized countries. Anemic mother is more likely to succumb to the ill effects of hemorrhage, be susceptible to infection and suffer from congestive cardiac failure.
(Progress in obstet and gynaecol, STUDD volume 15).

WHO criteria for diagnosis of anemia in pregnancy is Hb content of < 11 gm/dl. (7.45 mmol/l) and hematocrit of less than 0.33. CDC (Centers for Disease control, USA) proposes a cut off point of 10.5 gm/dl during the Second Trimester.
(Progress in obstet and gynaecol, STUDD volume 15).

ICMR categories of anemia. (Progress in OBG, STUDD volume 15)

Category	Severity	Hb level (gm/dl)
1.	Mild	10.0 - 10.9
2.	Moderate	7.0 - 10.0

3.	Severe	< 7.0
4.	Very severe	< 4.0

IRON DEFICIENCY ANEMIA;

Prevalence of anemia in pregnancy

Anemia affects about 18% of women during pregnancy in industrialised countries while in non-industrialised countries prevalence varies between 35-75% average being 56%. Incidence of anemia in India ranges between 20 and 30% in the middle income group and much higher in low income group(60%) and 70% in rural women.

(Progress in OBG, STUDD volume 15)

Iron Requirements in Pregnancy

Basal iron	-	280mg,
Expansion of red cell mass	-	570mg
Transfer to the fetus	-	200-350 mg
Placenta	-	50-150 mg
Blood loss at delivery	-	100-250 mg

After deducting iron conserved by amenorrhoea (240-480 mg) an additional 500-600 mg of iron is required in pregnancy or 4 – 6 mg/day of absorbed iron i.e 2.5mg/day in early pregnancy, 5.5mg/day from weeks 20 – 32 and 6 – 8 mg/day from weeks 32 onwards).

As absorption is less than 10% atleast 40 - 60mg of iron should be available in the diet.

Causes of high prevalence of Iron deficiency anemia;

1. Increased iron requirement
2. Dietary habits

Consumption of low bio availability diet, also higher in both Hindu vegetarian and Muslim (Halal Meat eaters), this could be due to loss of significant amounts of heme blood from the Halal meat where the animal is slaughtered by cutting its carotid artery and bled to death.

(Sharma and Soni 1999).

3. Defective iron absorption due to intestinal infection like hook worm, schistosomiasis, chronic malaria.
4. Menorrhagia / Bleeding from the gut due to haemorrhoids.

Stages of Iron deficiency anemia;

Stage I : Negative iron balance

Demands for iron exceed the body ability to absorb iron from diet.

Normal Hb / hematocrit level

Normal RBC indices

Serum .Ferritin < 20ng/ml

Stage II : Iron deficient Erythropoiesis

When stores become depleted serum iron begins to fall, total iron binding capacity rises gradually and once the transferrin falls to 15 to 20%, Hb synthesis becomes impaired.

Stage III : Iron deficiency anemia

Peripheral picture reveals microcytic and hypochromic cells appearing as vacuolated red blood cells with reticulocytes in circulation. Gradually Hb and hematocrit begins to fall. Transferrin saturation< 15%.

Clinical Features

Patient may be asymptomatic especially in mild and moderate anemia. Patient may complain of weakness, exhaustion, lassitude, indigestion, loss of appetite, palpitation, dyspnoea, giddiness and edema. Congestive cardiac failure can occur in severe cases.

Signs:

There may be no signs especially in mild anemia. There may be Pallor, glossitis and stomatitis. Patient may have edema due to hypoproteinemia. Soft systolic murmur can be heard in mitral area due to hyperdynamic circulation. There can be fine crepitations at bases of lungs due to congestion.

Effects of anemia on pregnancy

Maternal effects

Mild anemia may not have any effect on pregnancy and labour except that the mother who has low iron stores, may become moderate to severely anemic in subsequent pregnancies. Moderate anemia may cause increased incidence of preterm labour (28.2%), Pre-eclampsia (31.2%) and sepsis.

During labour there is an increased incidence of postpartum hemorrhage and congestive cardiac failure.

During puerperium there is an increased chance of puerperal sepsis, sub involution, failing lactation and venous thrombosis.

Fetal effects

Irrespective of maternal iron stores, fetus tends to obtain iron from maternal transferrin. But gradually the fetal iron stores becomes depleted. So Baby's born to anemic mother should be started on oral iron in the infancy itself.

Iron deficiency anemia is a significant risk factor for prematurity and Low birthweight infants if it is present in first trimester. In 2^{nd} and 3^{rd} trimester it had little effect on these fetal outcomes. (School et al).

Lozoff et al observed a significant effect of anemia on the affective behavior of an anemic child.

Diagnosis

Although the assessment of iron status in human population is advanced compared with other nutrients, there is still a large uncertainty about absolute diagnosis during pregnancy. (Am J Clin Nutr. 1994 : 59 (Suppl) 5025 – 10s).

Parameters	**Normal**	**-ve iron balance**	**Iron deficient erythropoiesis**	**Iron deficiency anemia**
Marrow iron stores	1 – 3 +	0 – 1 +	0	0

Serum ferritin(ng/ml)	50 – 200	< 20	< 15	< 15
TIBC (mg/dl)	300 – 360	> 360	> 380	> 400
Serum iron (mg/dl)	50 – 150	normal	<50	< 30
Saturation (%)	30 – 50	normal	< 20	< 10
Marrow sideroblasts (%)	40 – 60	normal	< 10	<10
RBC protoporphyrin (mg/dl)	30 – 50	normal	>100	>200
RBC morphology	normal	normal	normal	Microcytic hypochromic

Red cell indices

MCV is the first to get reduced and is the most sensitive indicator of iron deficiency anemia. MCHC is reduced in more severe cases of iron depletion.

	Normal	**Iron deficiency anemia**
MCV (fl)	75.96	reduced
MCHC (g/dl)	32.35	reduced

Lipshitz et al showed that for each grade of marrow iron, the serum ferritin concentration were 3 times higher in patients with infection than in control subjects. Thus the absolute cutoff of 12 – 15 mg/l may not include iron deficiency in individuals with inflammation.

Skikne et al showed that the serum transferrin receptor is a sensitive index of tissue iron deficiency and is relatively unaffected by inflammation or stage of pregnancy.

Prophylactic Supplementation

WHO recommendation based on the prevalence of anemia

< 40% : 60mg elemental iron and 0.4mg of folic acid.

> 40% : supplemented for another 3 months postpartum.

National nutritional anemia control programme guidelines.

100mg of elemental iron and 0.5mg of folic acid for minimum of 100 days, starting in the 2nd trimester and continued 3 months postpartum.

Schultink et al observed that <50% of the women who said they were taking the supplements and who knew they would be tested for a response actually did take their supplements as proved by iron positive stools.

Treatment of iron deficiency anemia

Iron deficiency aemia is the main cause of anemia during pregnancy. Iron should be the mainstay of therapy oral, parentral or through transfusion.

Breymann 2005 explained that the efficacy of oral and intramuscular iron is limited in many patients due to dose dependent side effects, lack of compliance and insufficient duodenal iron absorption, and correction of hematological and iron status parameters are still lacking.

Breymann 2005 also stated that transfusion has many problems including transmission of viruses and bacteria, RBC quality can be compromised during storage and the possibility of transmitting prions is an increasing worry.

Breymann 2005 maintained that following I.V iron sucrose administration it is not

necessary to survey the patient (or) monitor their blood pressure, the patient can leave with 100% compliance.

The increased availability of multiple parenteral iron preparations should decrease the need to use red cell transfusions in patients with Iron deficiency anemia. (Am. J. Hematol 76 : 76 – 78, 2004).

PHARMACOLOGY OF

INTRAVENOUS IRON SUCROSE

Iron Sucrose

Chemical Formula

$[Na_2\ Fe_5O_8\ (OH)\ 3\ (H2o)]_n\ .\ m(C_{12}\ H_{22}\ O_{11})$

Iron sucrose is a brown, sterile, aqueous complex of polynuclear iron (III) hydroxide in sucrose containing 20mg elemental iron per ml.

The sterile solution has an osmolarity of 1250 mosm/l. The product does not contain preservatives.

Molecular wt : 34,000 – 60,000 daltons

P_H : 10.5 – 11.1

Mechanism of action

Following intravenous administration, it is dissociated into iron and sucrose by reticulo endothelial system and iron is transferred from the blood into pool of iron in the liver and bone marrow. Ferritin sequester iron in a nonionic form from which iron is easily available.

Pharmacokinetics ;

Its iron component exhibits first order kinetics

Elimination t ½	:	6 hrs
Total clearance	:	1.2 litres / hour
Non – steady state apparent volume of distribution	:	10 lit
Steady state apparent volume of distribution	:	7.9 lit.

Distribution

In healthy adults, its iron component appears to distribute mainly in blood and to some extent in extra cellular fluid.

Elimination

The sucrose component is eliminated mainly by urinary excretion. Some iron is also eliminated in the urine. (approximately 5%)

Side effects

Headache, fever, pain, asthenia, malaise, abdominal pain.

Interaction

Should not be administered concomitantly with oral iron preparation since the absorption of oral iron may be reduced.

Contraindications

1. Evidence of iron over load.
2. Anemia not caused by iron deficiency
3. Known hypersensitivity to I.V iron sucrose (or) any of its inactive compounds.

Method and route of administration

No test dose is required

1. Slow IV injection

100mg (2amp) to be given undiluted over a period of 2 – 5 min.

2. Slow IV infusion

100mg (2amp) to be diluted with 100ml of normal saline immediately prior to infusion and to be infused over a period of atleast 15min (6mg/min).

Dosage frequency

100mg/day given on alternate days until the required dose is infused.

Chandler et al observed that optimal doses of 200 – 300mg infused intravenously over 2 hrs were well tolerated and safe. Patients who received doses of 400 – 500mg intravenously over 2 hrs experienced hypotension, nausea, and low back pain.

Supply and storage

Supplied in 2.5ml single dose vial. Each 2.5ml vial contains 50mg of elemental iron (20mg/ml), that is packaged in carton containing 10 single dose vials. Stored at 25^0C. Excursions permitted to 15 – 30^0C.

Pharmacology of Intramuscular
Iron Dextran

Iron dextran is a dark brown slightly viscous sterile liquid of ferric hydroxide and dextran, containing 50mg of elemental iron per ml.

Molecular Weight	:	165,000 g/mmol
PH	:	5.2 to 6.5

Mechanism of action

Following intramuscular administration it is absorbed into capillaries and lymphatic system and the circulating iron is removed from the plasma by reticulo endothelial system, which split the complex into iron and dextran.

Iron is bound to available protein moieties to form hemosiderin or Ferritin.

Encouraging results were obtained only with low molecular weight dextran. I.M iron

preparations has been made which is well absorbed with low toxicity. (Fletcher and London 1954).

Elimination

Dextran, a poly glucose which is either metabolised or excreted. Only negligible amount is lost via urinary / alimentary pathway but major portion is absorbed in 72hours.

Side effects

Severe / fatal : Anaphylactic reactions

Cardiovascular system : Chest pain, hypotension, shock.

Dermatological : Urticaria, pruritis, purpural rash

Hematological : leucocytosis / lymphadenopathy

Neurological : Convulsions, seizure, headache.

Delayed : Arthralgia, backache, chills ,fever,
Headache, myalgia.

Precautions

H/o significant allergy / asthma.

Oral iron should be discontinued prior to administration.

Supply and storage

Supplied as 50mg of elemental iron per ml in 2ml single dose amber vials in cartons of 10 which is stored at 20 – 25^{0}C (68 – 67^{0}F).

Iron dextran does not precipitate with change of p^H, therefore buffering action of blood does not affect its stability.

(Cappell 1930 and Nission 1935)

Method and Route of Administration

Test dose : 0.5ml is given in the same recommended site and by the same technique. Although anaphylactic reactions known to occur, which usually evident in few min. It is recommended that atleast an hour or longer elapse before the remainder of the therapeutic dose is given.

100mg of elemental iron (2ml) is given as deep intramuscular injection into the upper outer quadrant of the buttock using a Z technique .(Pulling the skin and subcutaneous tissue to one side before inserting the needle).

MATERIALS AND METHODS

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This prospective randomised controlled study was undertaken at Government Rajaji Hospital attached to Madurai Medical College in obstetrics and Gynaecological department. 50 antenatal patients with gestational age between 28 – 34 wks attending antenatal OPD and 50 postnatal patients with iron deficiency anemia (Hemoglobin between 7 – 9gm/dl) were selected which includes both booked and unbooked cases.

Inclusion Criteria for the Patients

Following criterias were utilised in selecting patients for this study

1. Age 18 – 45 yrs
2. Singleton pregnancy between 28 to 34 wks
3. Hb < 11gm/dl or hematocrit < 33%.

Exclusion Criteria

1. Underlying disease such as hypertension, gestational diabetes, heart disease, peptic ulcer.
2. H/o allergy to iron containing medication.
3. H/o other allergic conditions or asthma.
4. Thalassemia.
5. H/o Bleeding tendency.
6. H/o blood transfusion with in prior 120 days.

After confirming iron deficiency anemia using peripheral smear, antenatal and postnatal

patients with iron deficiency anemia who fulfilled the above said criteria were randomly allocated into 2 groups. Group A and group B. Group A contains 25 antenatal and 25 postnatal patients and group B contains 25 antenatal and 25 postnatal patients.

After obtaining an informed consent, a detailed history taking and complete general examination and detailed obstetric examination were done.

METHOD OF THE STUDY

Calculation of iron requirement

Iron requirement is calculated using the following formula

Antenatal patients ;

2.4 x (target Hb – patient Hb) x

pre pregnancy Weight (kg) + 500 (Storage iron) = mg

No need for test dose.

Group A patients were given intravenous iron sucrose complex, 100mg of elemental iron diluted in 100ml of 0.9% normal saline was infused over 15min daily until the required dose was infused.

Group B patients were given intramuscular iron dextran 100mg [lamp contains 2ml] as deep intramuscular injection into the upper outer quadrant of buttock using Z technique'. (Pulling the skin and subcutaneous tissue to one side before inserting the needle).

Additional precautions were taken to prevent even a slight drop of solution to come beneath the skin surface by injecting small quantity of air or Saline down the needle before withdrawing it. Given daily until the required dose was infused.

Observations

During therapy the following parameters were monitored

1. Vitals (Pulse, BP, Temperature)
2. Adverse effects like nausea / vomitting / abdominal pain, chills etc.
3. Anaphylactic reactions.

The following investigations were done before therapy to asses the degree of anemia.

1. Hb
2. Hematocrit.
3. MCV

Patients were advised to attend our OPD 3 weeks after therapy and the following parameters were assesed.

1. Symptomatic improvement
2. Hb
3. Hematocrit.
4. MCV

RESULTS

OBSERVATIONS AND RESULTS

This study was conducted in 100 patients (50 antenatal and 50 postnatal patients) and they were randomly allocated into 2 groups. Group A and group B. Group A contains 25 antenatal and 25 postnatal patients. Group B contains 25 antenatal and 25 postnatal patients.

Group A : Received intravenous iron sucrose 100mg per day diluted in 100ml of 0.9% normal saline till the required dose was infused.

Group B : Received I.M iron dextran 100mg per day deep I.M in gluteal region till the required dose was infused.

CHARACTERISTICS OF CASES STUDIED

Table 1

Age distribution

Age Group	Intravenous Group		Intramuscular Group		Total %
	No	%	No	%	
Less than 20 years	4	8	11	22	15
21 – 25 years	31	62	18	36	49
26-30 years	12	24	12	24	24
Above 30 years	4	8	8	16	12
Total	50	100	50	100	100

Mean S.D	24.62 4.2	25.0 5.07	
'p'	0.9779 Not Significant		

There were no significant difference among the groups regarding age distribution as shown in table 1

Among 100 women studied, 15% (15/100) were less than 20yrs, 49% (49/100) of patients belongs to the age group. 21 – 25yrs, 24% (24/100) belongs to age group 26 – 30yrs, 12% belongs to age >30yrs. The mean age was 24.62 and 25 in group A and group B respectively.

AGE DISTRIBUTION

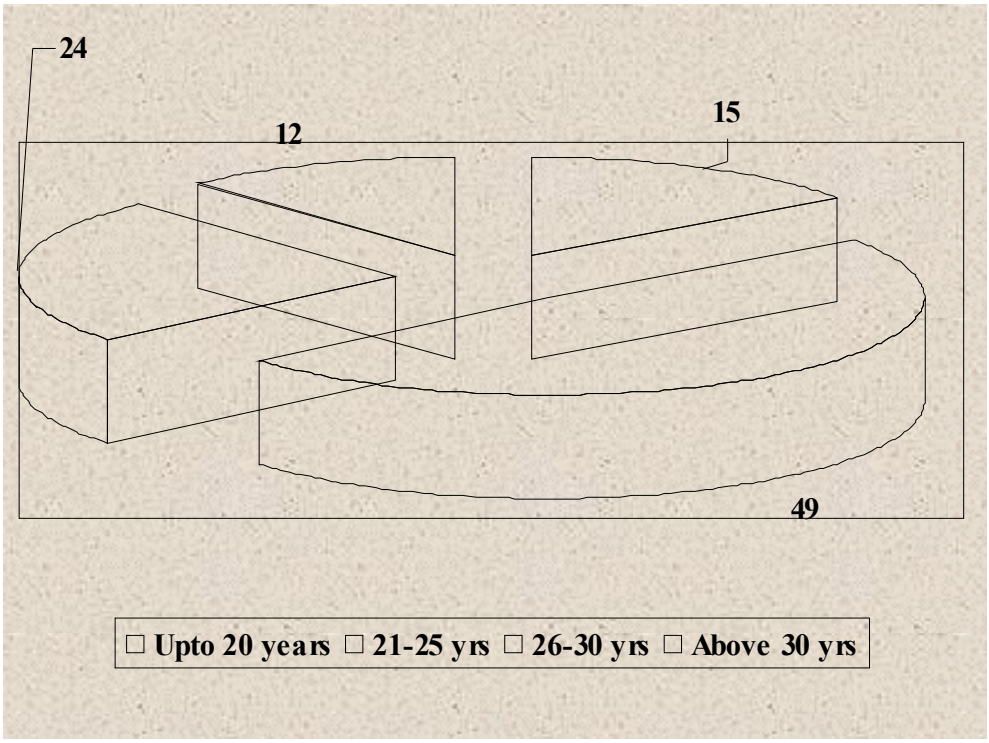
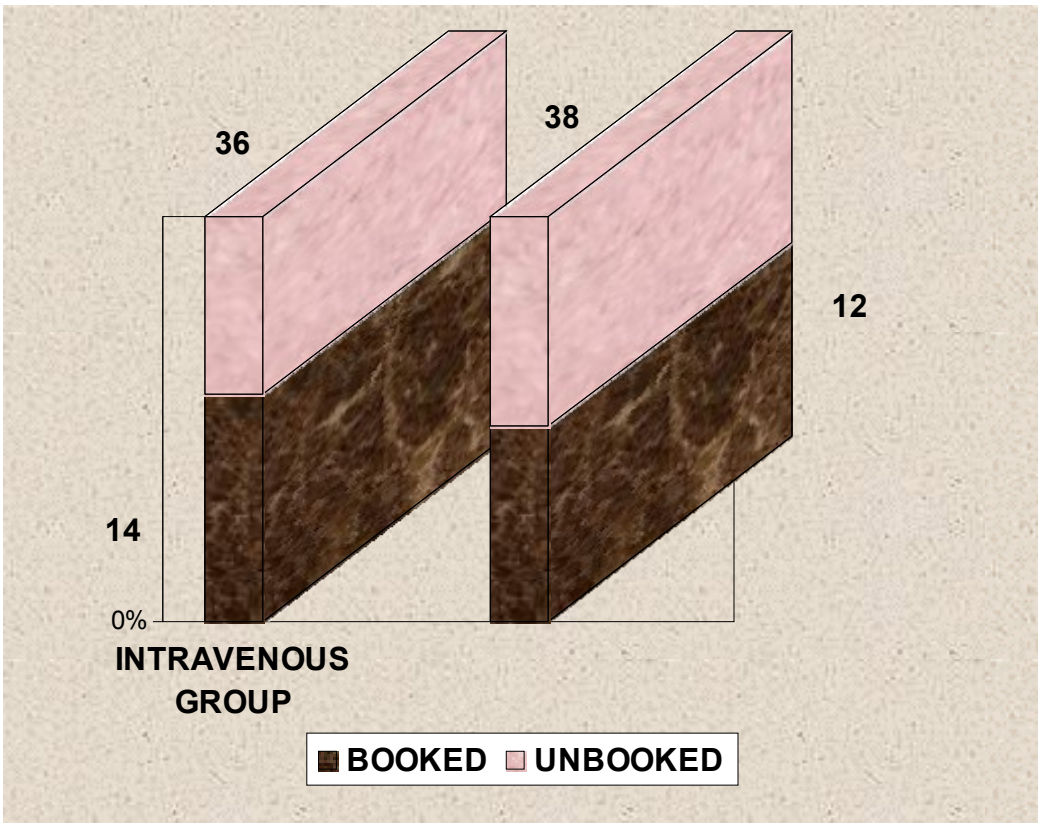


Table 2

Booking Status

Booking Status	Intravenous Group		Intramuscular Group		Total
	No.	%	No.	%	%
Booked	12	24	14	28	26
Unbooked	38	76	36	72	74
'p'	0.8197 Not significant				

Among the 100 women studied 74% were unbooked, 26% were booked. Booked and unbooked cases were equally distributed in 2 groups.



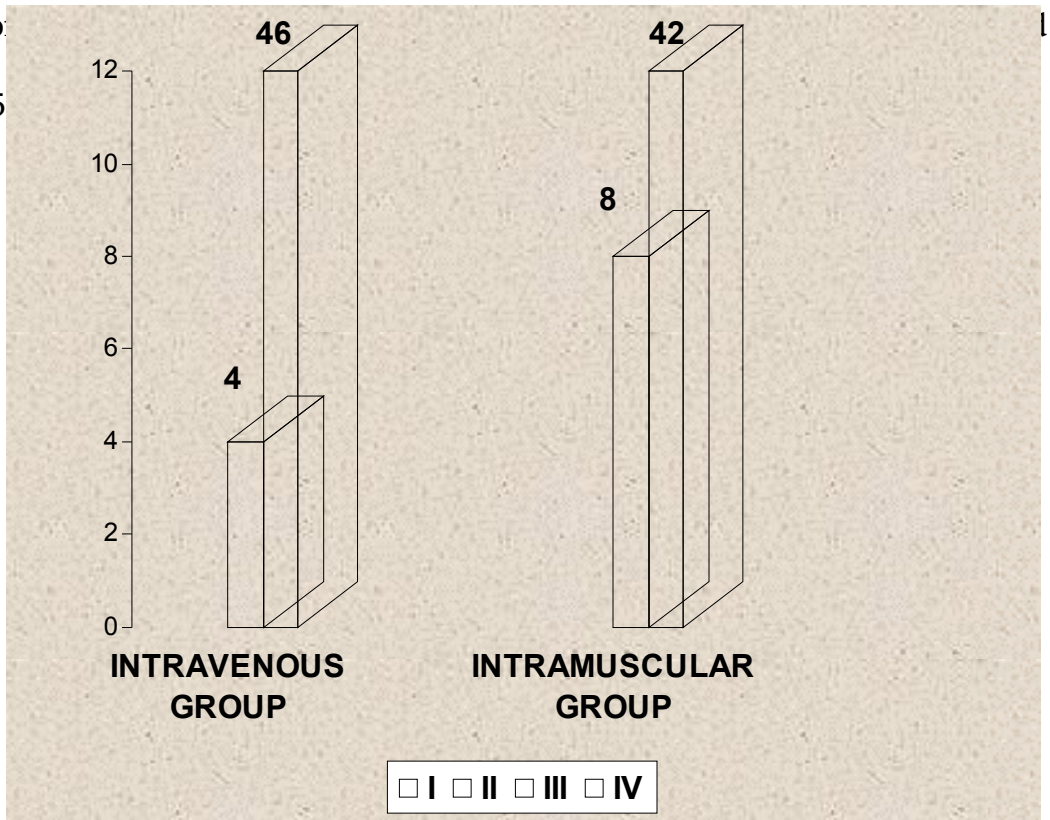
Among the 50 patients in group A 12/50 (24%) were booked, 38/50 (76%) were unbooked. In group B 14/50 (28%) were booked and 36/50 (72%) were unbooked.

Table 3

Socio economic Status

Socio economic Status	Intravenous Group		Intramuscular Group		Total
	No.	%	No.	%	%
Class I	-	-	-	-	-
Class II	-	-	-	-	-
Class III	4	8	8	16	12
Class IV	46	92	42	84	88
'p'	0.3559 Not significant				

88% of women belonged to class IV socioeconomic status. 12% belonged to class III Socio economic class. None of the patients belonged to class I and class II group.



Among 50 patients in group A 4/50 (8%) belonged to class III and 46/50 (92%) belo l to class III and 42/5

Table 4

Parity

Parity	Intravenous Group		Intramuscular Group		Total
	No.	%	No.	%	%
Primi	18	36	18	36	36
Multi	32	64	32	64	64

Among the 100 women studied 36% were primipara 64% were multipara, 64% were para 2 and above. Both primi and multipara were equally distributed in both groups.

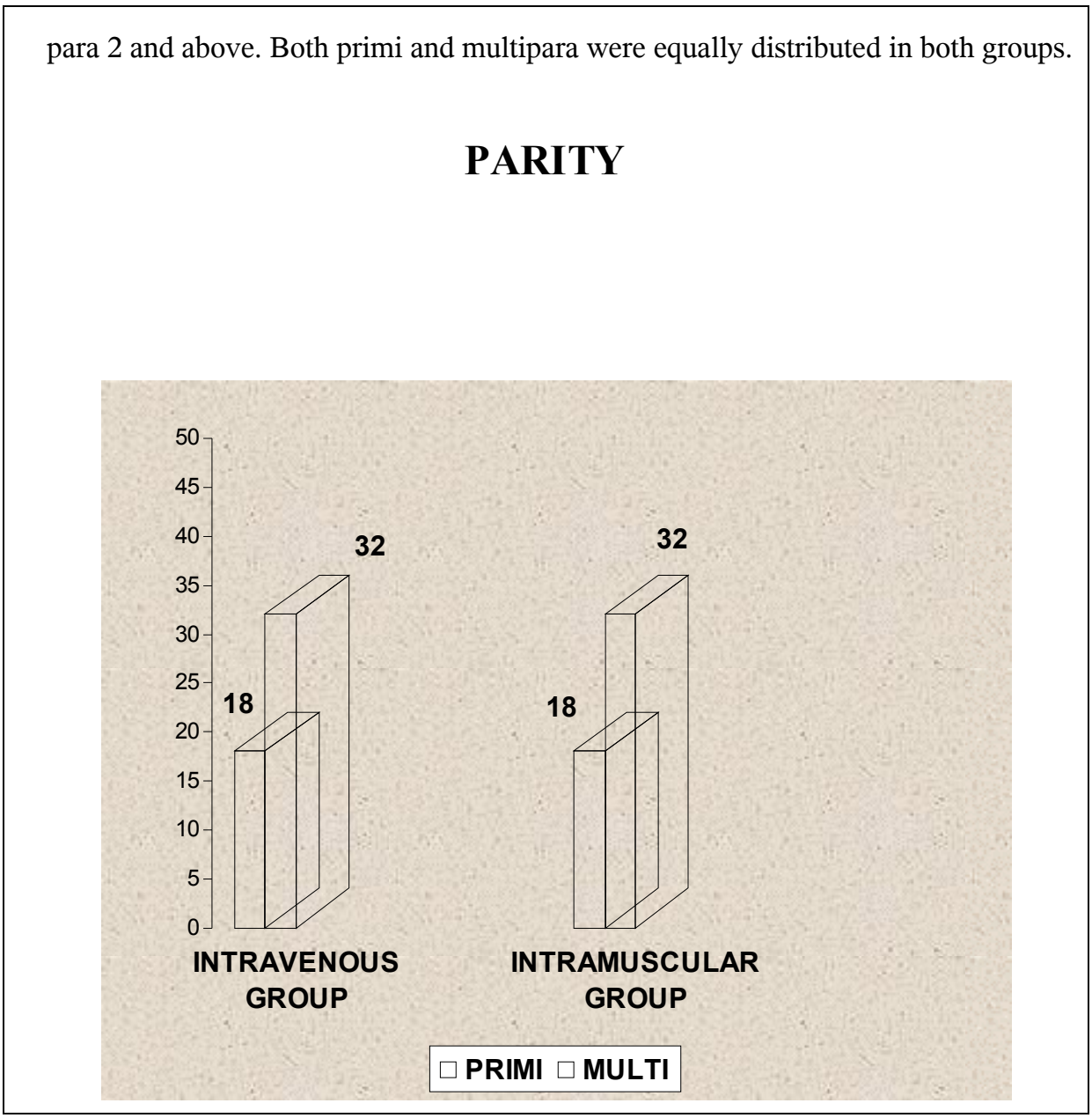


Table 5

Symptoms

Symptoms	Intravenous Group		Intramuscular Group		Total
	No.	%	No.	%	%
Asymptomatic	36	72	28	56	64
Easy fatiguability	10	20	12	24	22
Breathlessness (GradeI)	6	12	8	16	14
Pallor of skin & Mucous membrane	16	32	10	20	26
Menstrual problems	3	6	4	8	7

Among the 100 women studied 64 patients (64%) were asymptomatic, 22% presented with easy fatiguability, 14% with Breathlessness (Grade I), 7% with menstrual problems, and 26% patients showed pallor of skin and mucous membrane.

Table 6

Symptomatic well being (improvement)

Symptoms	Intravenous Group		Intramuscular Group		'p'
	No.	%	No.	%	

Easy fatiguability	10/10	100	3/12	25	**0.0015** **Significant**
Breathlessness	5/6	83.3	4/8	12.5	**0.0163** **Significant**
Pallor	16/16	100	4/10	10	**0.0001** **Significant**

Among 10 patients with easy fatiguability and 6 patients with Breathlessness (Grade I) and 16 patients with pallor, all (100%) experienced improvement of symptoms after treatment, whereas in iron dextran group among 12 cases with easy fatiguability and 8 cases with breathlessness (Grade I) only 3/12 cases and 4/8 cases respectively experienced improvement of symptoms. Thus statistically significant difference of improvement in symptoms in intravenous group when compared to intramuscular group. P value showed statistically significant difference.

SYMPTOMATIC WELL BEING

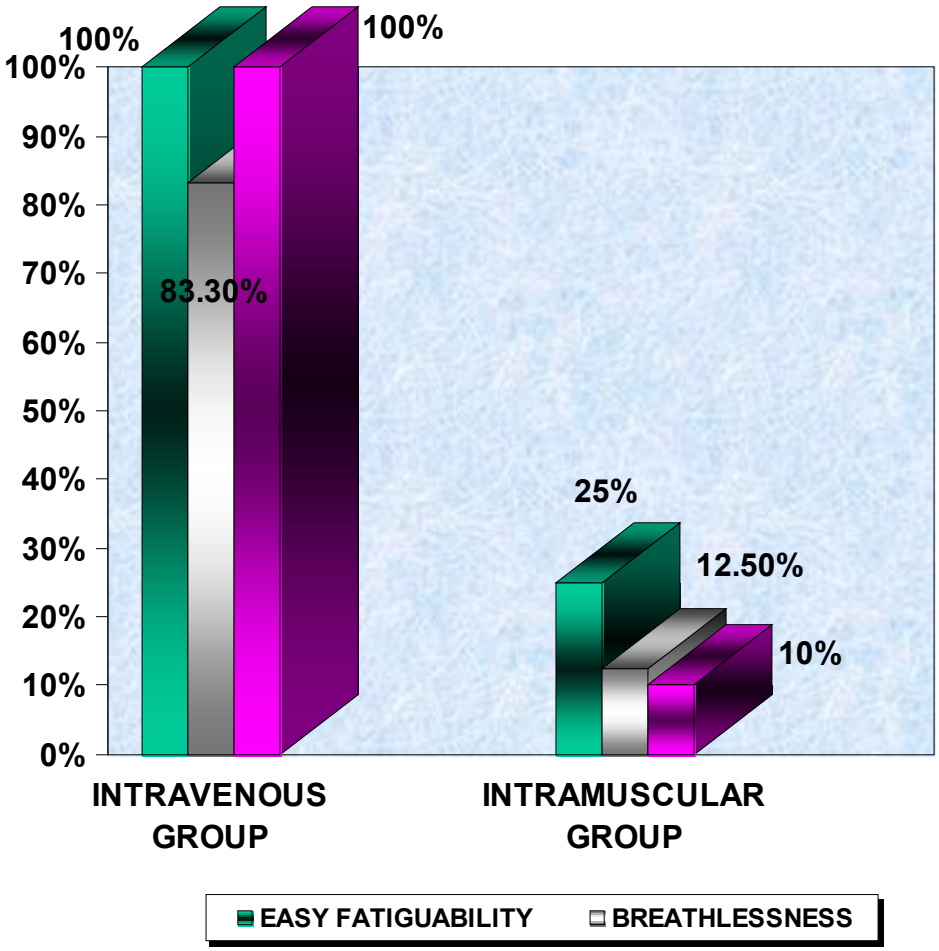


Table 7

Change in Hb.%

Hb.%	Intravenous Group		Intramuscular Group		'p'
	Mean	S.D	Mean	S.D	
Before treatment	7.88	0.51	7.86	0.43	0.7619 Not significant
After treatment	10.84	0.56	9.19	0.36	**0.0001** **Significant**
Change in Hb.%	2.97	0.55	1.36	0.35	**0.0001** **Significant**

Mean Hb in group A and group B was 7.88 gm/dl and 7.86 gm/dl respectively. Post therapy Hb after 3 weeks showed an mean Hb value of 10.84% gm/dl and 9.19 gm/dl respectively (P value : 0.001), which was statistically significant. The average rise of Hb was 2.97 gm/dl and 1.36 gm/dl respectively (P value 0.001), which was statistically significant. Targ

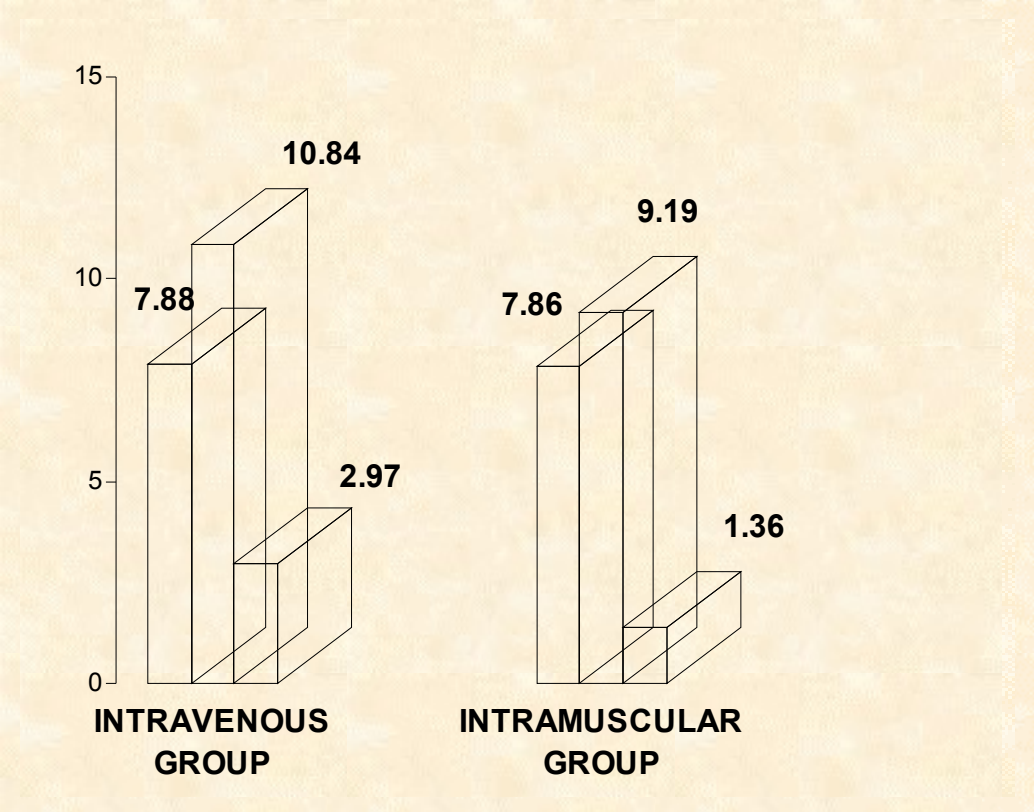


Table 8

Change in Hematocrit

Hematocrit	Intravenous Group		Intramuscular Group		'p'
	Mean	**S.D**	**Mean**	**S.D**	
Before treatment	30	2.5	31.4	1.7	0.9619 Not significant
After treatment	41.3	4.7	36.8	1.9	**0.0342** **Significant**
Change in	11.3	2.8	5.4	1.3	**0.0001**
Hematocrit					**Significant**

Among 100 patients studied hematocrit in Group A and Group B was 30 and 31.4 respectively. Post therapy hematocrit after 3 weeks showed an mean hematocrit value of 41.3 and 36.8 respectively. P value is 0.0342, which was statistically significant and the average rise of hematocrit was 11.3 and 5.4 in group A & B respectively, which was statistically significant.

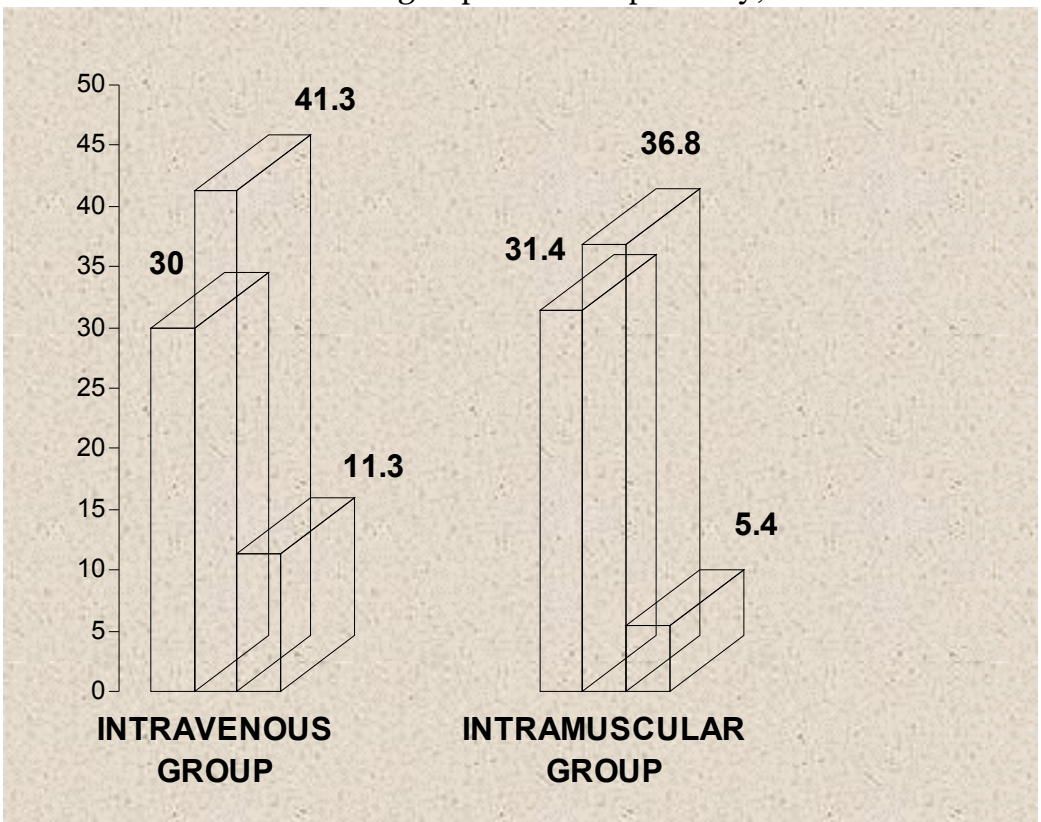


Table 9

Change in MCV

MCV	Intravenous Group		Intramuscular Group		'p'
	Mean	**S.D**	**Mean**	**S.D**	
Before treatment	68.2	6.3	66.6	4.7	0.7619 Not significant
After treatment	83.9	5.8	74.8	6.1	**0.0023** **Significant**
Change in MCV	15.6	6.7	8.2	5.5	**0.0001** **Significant**

Among 100 patients studied mean MCV in group A and group B was 68.27 fl and 66.6 fl respectively. Post therapy assesment after 3 weeks in group A and group B showed as mean MCV value of 83.9 fl and 74.8fl respectively, (P value 0.0023) which was statistically signi A and group B resp

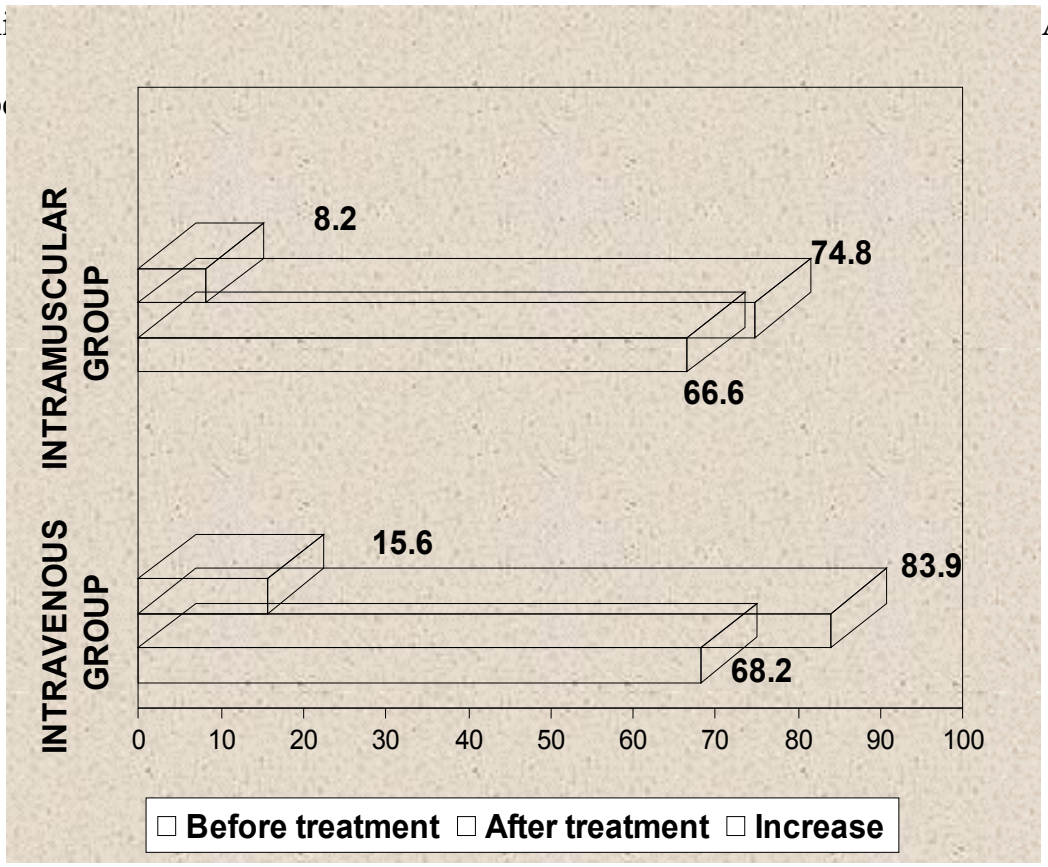
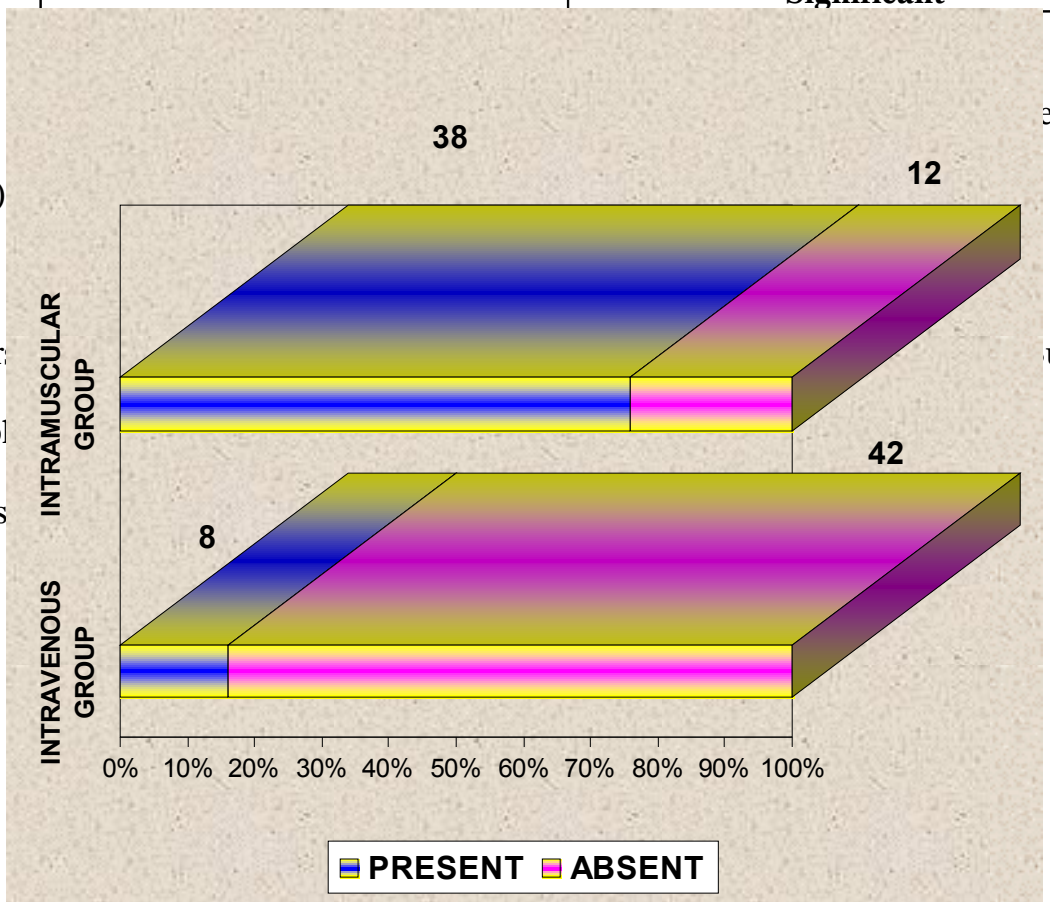


Table 10

Adverse effects of the drug

Adverse effects of the drug	Intravenous Group		Intramuscular Group	
	No.	%	No.	%
Headache	2	4	4	8
Nausea/ Vomitting	-	-	-	-
Abdominal pain	1	2	6	12
Chills/rigors	4	8	12	24
Joint pain	-	-	32	64
Anaphylactic reaction(Hypotension)	-	-	-	-
Thrombophlebitis	1	2	-	-
Pain at the injection site	-	-	38	76
Patients with adverse effects	8	16	38	76
Patients without adverse effects	42	84	12	24
'p'	**0.0001** **Significant**			

ADVERSE EFFECTS OF THE DRUG



e headache 2/50 (4%) (2%) and more side (76%), chills / rigor ut there was no anapl reactions were statis

Table 11

Complaince

Complaince	Intravenous Group		Intramuscular Group	
	No.	**%**	**No.**	**%**
Discontinued treatment due to adverse effects	Nil	-	10/50	20
Not come for follow up	4/50	8	8/40	20

Among 50 patients in intravenous group none of the patients discontinued the treatment due to adverse effects, where as in intramuscular group among 50 patients 10 patients 10/50, discontinued the treatment due to adverse effects.

Among 50 patients in intravenous group 4 cases 4/50 (8%) did not come for follow up, where as in intramuscular group 8 patients 8/40 (20%) did not come for follow up.

Statistical Tools

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using ***Epidemiological Information Package (EPI 2002).***

Using this software, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance

of difference between quantitative variables and Yate's test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

DISCUSSION

DISCUSSION

In this study 100 patients (50 antenatal and 50 postnatal) with iron deficiency anemia were selected according to the inclusion and exclusion criteria stated in methodology. They were divided into 2 groups (50 patients each).

In group A, patients were given injection intravenous iron sucrose 100mg I.V. infusion per day until the calculated dose was infused.

In group B, patients were given injection intramuscular iron Dextran 100mg I.M. per day until the calculated dose was infused.

The distribution of patients as per Age, Parity, Booking Status and Socioeconomic status were equal in 2 groups, so that the results can be predicted with accuracy.

In our study 16% (16/100) of the patients were upto 20yrs. 49% (49/100) of the patients were in the age group of 21 – 25 yrs. 23% (23/100) of the patients were in the age group of 26 – 20yrs and 12% (12/100) of the patients were > 30yrs.

In our study 74% of the patients were unbooked and 26% were booked. Booked and unbooked cases were equally distributed in 2 groups. .

In our study 84% of women belonged to class IV socio economic status and 16%

belonged to class III socioeconomic status. Majority were in low socio economic group.

In our study 32% of the patients were primipara and 68% were multipara. Majority were in multipara group.

In our study 64% were asymptomatic, 22% presented with easy fatiguability, 14% presented with breathlessness (Grade I), 10% presented with menstrual problems. 26% showed pallor of skin and mucous membrane. Thus 64% of patients were asymptomatic in our study.

In our study all patients (100%) were experienced symptomatic well being in intravenous group, when compared to intramuscular group in which among 12 cases with easy fatiguability and 8 cases with breathlessness (Grade I) only 3 cases and 4 cases respectively were experienced improvement of symptoms.

P value is 0.0001. Thus statistically significant difference observed between 2 groups.

Comparison of outcome parameters

Changes in Hemoglobin:

In our study, hemoglobin level was measured before treatment and again after 3 weeks post therapy assesment was done using sahli's hemoglobinometer at GRH laboratory.

Mean Hb in group A and group B was 7.88% and 7.86%, respectively. Post therapy Hb after 3 weeks showed an mean Hb value of 10.84 gm% and 9.19gm% respectively. P value is 0.001 which was statistically significant.

An average rise in Hb was 2.97 gm% and 1.36 gm% (p value 0.001), which was statistically significant and target Hb was achieved in 80% of women in group A and 20 % of women in group B.

According to study by Walia et al J Pak med Assoc. 2002 Sep; a prospective comparative study included a total number of 40 pregnant women with gestational age of 12 – 34 weeks showed a mean hemoglobin in group A and group B was 8.0 +/- 1.1 gm% and 8.8 +/- 0.9 gm% respectively, post therapy Hb after 3 weeks showed an average rise of 2.8 gm% in group A and 1.4 gm in group B. Target Hb (11 gm/dl) was achieved in 80% in group A and 28% in group B patients. Our study was comparable with above mentioned study.

Our study was comparable with study by Ann Pak Inst. med sci. Sep 2006; Zahana hospital attached and Hashmi maternity clinic Dera Ismail Khan, a randomised controlled study showed a total rise of 2.6gm% in group A and 1.2gm% in group B. Target Hb level was achieved in 80% of group A and 20% of group B patients.

Another study by Bayoumeu et al, American Journal of Obstetrics and Gynaecology March 2002, showed an increase in Hb 3 weeks after therapy from 9.6 +/- 0.79 gm%/dl to 11.11+/- 1.3 gm%/dl in intravenous group and from 9.7+/- 0.5 gm% to 11+/- 1.25 gm% in oral group. This was statistically not significant.

Change in hematocrit

In our study, the mean hematocrit in group A and group B was 30 and 31.4 respectively.

Post therapy hematocrit assesment after 3 weeks showed an mean hematocrit value of 41.3 and 36.8 respectively.

P value is 0.0342. This was statistically significant.

The average rise of hematocrit was 11.3 and 5.4 in group A and B respectively, which was statistically significant.

Change in MCV

In our study mean MCV in group A and group B patients were 68.2 fl and 66.6 fl respectively. Post therapy assesment showed an mean MCV value of 83.9 fl and 74.8 fl respectively.

P valuve is 0.0023 which was statistically significant and the average rise in MCV was 15.7 fl and 8.2 fl in group A and group B respectively.

A study by Mrs. Khurshid Shabhir Raja et al, journal of the Pakistan Medical Association Volume 28, Number 2 july- Dec 2003 showed mean MCV before treatment was 65 fl, mean MCV 3 weeks post therapy showed 75fl and the mean rise in MCV was 10 fl with p value <0.5 which was statistically significant. This study was comparable with our study.

Adverse reactions of the Drugs

In our study side effects were minimal in group A 16% like headache 2/50 (4%),

abdominal pain 1/50 (2%), chills and rigors 4/50 (8%) Thrombophlebitis 1/50 (2%), compared to more side effects in group B patients like joint pain 32/50 (64%), pain at the injection site 38/50 (76%), chills and rigors in 12/50 (24%), and abdominal pain in 6/50 (12%) of the patients. There were no anaphylactic reactions noted in both groups.

Study by WaliA et al J pak med Assoc. 2002 showed out of 20 patients one patient had moderate abdominal pain and 2 had weakness and shivering and 3 had phlebitis. In intramuscular group majority complained of pain at the injection site. This study was comparable to our study.

Complaince;

In our study among 50 patients in intravenous group none of the patients discontinued the treatment due to adverse effects.

Study by WaliA et al showed that none of the patients in intravenous Group discontinued the therapy due to any adverse effects. This study was comparable to our study.

In our study among 50 patients in intravenous group 8%(4/50) did not come for follow up assesment, where as in intramuscular group 8 patients 8/40 (20%) did not come for follow up.

Study by Walia A et al showed that 20% of the patients dropped out from the study out of 25 patients due to intolerance. This study was comparable to our study.

SUMMARY

S U M M A R Y

100 patients (50 antenatal patients attending antenatal OPD and 50 postnatal patients after delivery) with iron deficiency anemia between September 2007 to September 2008 at Government Rajaji Hospital were selected according to inclusion and exclusion criteria, already stated in methodology were taken for this randomised controlled study.

They were allocated into 2 groups of each group A (no. 50; 25 antenatal & 25 postnatal) and group B (no 50; 25 antenatal and 25 postnatal)

Group A patients were given intravenous iron sucrose and group B patients were given intramuscular iron dextran.

Patients were advised to attend our OPD 3 weeks after therapy and the following parameters were assesed.

1. Symptomatic improvement
2. Hb
3. hematocrit
4. MCV.

The results of the study are tabulated, analysed and summarised as follows:-

1. Majority of the patients around 49% belongs to the age group between 21 – 25 yrs in both group A and group B.

2. Almost three fourth of the patients were unbooked (74%). Booked and unbooked cases were equally distributed in both groups.
3. Majority (84%) of the women belongs to class IV socio economic status in both group A and group B.
4. Majority around 68% were para 2 and above, both primi and multi were equally distributed in both groups.
5. Most of the patients around 64% were asymptomatic in both group A and group B.
6. Symptomatic well being observed in all cases (100%) of intravenous group but Only 20 – 30% of the cases in intramuscular group. P value is < 0.0001 the result was statistically significant.
7. Mean rise in Hb value was 2.97 gm/dl in intravenous group and 1.30 gm/dl in intramuscular group. P value is < 0.001. Which was statistically significant.
8. Target Hb was achieved in 82% of group A and 26% of group B patients, which was statistically significant.
9. Average rise in hematocrit value was 11.3 in intravenous group and 5.4 in intramuscular group (P value is < 0.0342) which was statistically significant.
10. Mean rise in MCV was 15.7 fl in group A and 8.2 fl in group B. P value is (< 0.0023) which was statistically significant.
11. The side effects were minimal in group A (16%) compared to 76% in group B. P value is < 0.0001, which was statistically significant.
12. None of the patients in group A discontinued the treatment due to adverse reactions, where as 20% of patients dropped out from the study in group B due to adverse reactions.

C O N C L U S I O N

CONCLUSION

1. Intravenous iron sucrose is highly efficacious in improving Hb, hematocrit values in the treatment of iron deficiency anemia in pregnancy and puerperium when compared to intramuscular iron dextran.

2. It is well tolerated and safe when compared to intramuscular iron dextran.

3. complaince of the patient is good in intravenous iron sucrose when compared to intramuscular iron dextran.

4. The side effects are minimal in intravenous group when compared to intramuscular group.

5. To conclude intravenous iron sucrose therapy is safe, convenient and more effective than intramuscular iron therapy in treatment of iron deficiency anemia.

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P R O F O R M A

PROFORMA

STUDY OF EFFECTIVENESSOF INTRAVENOUS IRON SUCROSE, Vs INTRAMUSCULAR IRON DEXTRAN IN IRON DEFICIENCY ANEMIA.

Name : Age :

IP No : Address :

Occupation :

Income :

Socioeconomic Class :

Obstetric table : LMP :

Gravida: EDD :

Para : Weeks of gestation :

Live :

Presenting complaints:

H/o Easy fatiguability / giddiness

H/o Hook worm infestation

H/o Bleeding per vaginum

H/o Hematemesis / malena

H/o Anorexia / indigestion

H/o Multiple pregnancy

H/o Breathlessness

H/o Swelling of legs

H/o Puffiness of face

H/o Iron intolerance

Past H/o

H/o Blood loss in between pregnancy

H/o DM, HT, Asthma, epilepsy, TB

Menstural H/o :

A/M at :

Cycles : Regular Irregular

flow :

Marital H/o:

M /s :

Obstetric History :

Details about previous pregnancy : Yes No

H/o Antepartum Hemorrhage

H/o Postpartum Hemorrhage

H/o Blood Transfusion

Present Pregnancy :

1. Gravida : M/s

Para : LCB :

Live

2. H/o Antepartum Hemorrhage

3. H/o Postpartum Hemorrhage

4. H/o Blood Transfusion

5. H/o Iron and Folic acid intake

General Examination :

Features of Chronic anemia : Yes No

1. Pallor :

2. Glossitis :

3. Facial Puffiness :

4. Koilonochia :

VITALS

PR - Cvs

Bp - Rs

Period of Gestation by clinical examination :

Period Gestation by USG :

Fetal heart rate :

Investigations :

To confirm iron deficiency anemia :

1. Hb :

2. Urine : Albumin

Sugar

Deposits

3. Blood : Sugar

Urea

Serum : Creatinine

5. Peripheral smear :

6. MCV

7. Hematocrit

8. Stool : Ova

Cyst

Iron Requirement :

Dose of intravenous iron sucrose needed & method of therapy :

Dose of intramusuclar iron-dextran needed & method of therapy :

Parameters monitored during therapy :

Adverse effects	Yes	No
1. Anaphylactic reaction (Shivering, Hypotension)		
2. Nausea / Vomitting		
3. Thrombophlebitis		

4. Abdominal Pain

5. Diarrhoea

6. Chills / Rigors

7. Joint pain

Post therapy Assesment :

Parameters Assesed 3 wks post therapy

1. Symptometic improvement
2. Hb
3. MCV
4. Hematocrit

ABBREVATIONS

WHO	-	World Health Organisation
Hb	-	Hemoglobin
MCV	-	Mean Corpuscular Volume
MCHC	-	Mean Corpuscular Hemoglobin Concentration
TIBC	-	Total Iron Binding Capacity
$Fe2^{+}$	-	Ferrous Iron
$Fe3^{+}$	-	Ferric Iron
SES	-	Socio Economic Status
F.U	-	Follow up
I.V	-	Intravenous
I.M	-	Intramuscular